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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,577	01/25/2000	John R. Carlson	044574-5061-US	8713

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EXAMINER	
MURPHY, JOSEPH F	
ART UNIT	**PAPER NUMBER**
1646	14

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/491,577	CARLSON ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-45* is/are pending in the application.

4a) Of the above claim(s) *11-26 and 37-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-36 and 43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Formal Matters

1. Claims 1-10 were cancelled, and new claims 27-45 were added in paper No. 12, 1/5/2002. Claims 11-26 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Newly submitted claims 37-42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are drawn to a polypeptide, which is classified in class 530, subclass 350, and is independent and distinct, because the claims are drawn to products which possess characteristic differences in structure and function, and each has an independent utility, that is distinct from the elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37-42 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 27-36, 43-45 are under consideration.

Response to Amendment

2. The objection to claims 3-10 has been rendered moot by cancellation of the claims.

Claim Rejections - 35 USC § 101/112 first paragraph

3. The rejection of cancelled claims 1-10 under 35 U.S.C. § 101, is applied to now pending claims 27-44, because they are drawn to an invention with no apparent or disclosed patentable utility, for reasons of record set forth in Paper No. 9, 6/29/2001. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or

its significance. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

According to MPEP § 2107, a rejection for lack of utility is imposed when an invention lacks an asserted specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

The basis of the rejection is that the nucleic acid encoding the alleged Drosophila odorant receptor with the sequence as set forth in SEQ ID NO: 31 has been isolated because of its similarity to known nucleic acids encoding known proteins, and the Doerks et al. reference was cited as evidence to establish the errors inherent in sequence-function methods of assigning protein function. Thus, given the errors inherent in sequence to function methods of assigning protein function, and the Mikayama et al. and Voet et al. references which demonstrates that the change of a single amino acid can radically alter protein function, and absent sufficient evidence to the contrary, a person of ordinary skill in the art would not immediately appreciate why the invention is useful.

Applicant argues in Paper No. 12, 12/31/2001, that the protein with the amino acid sequence as set forth in SEQ ID NO: 31 can be used for identify agents which affect receptor activity. However, this asserted utility is credible but not specific or substantial. Such assays can be performed with any polypeptide. Nothing is disclosed about how the polypeptide is affected by the compounds. Additionally, the specification discloses nothing specific or

substantial for the compound produced in this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Applicant also argues that the polypeptide can be used for the preparation of antibodies. However, this asserted utility is credible but not substantial or specific. Such methods can be performed with any polypeptide. Further, the specification discloses nothing specific or substantial for the antibodies which are produced by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Applicant presents a Declaration under 37 CFR 1.132, Paper No. 13, 12/31/2001, that the protein with the amino acid sequence as set forth in SEQ ID NO: 31 binds ethyl butyrate. However, the burden is on Applicant to provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing. The evidence submitted by Applicant is post-filing, therefore, a preponderance of the evidence demonstrates that at the time of filing, a nucleic acid encoding a polypeptide with the amino acid sequence set forth in SEQ ID NO: 31 lacked a well-established, specific and substantial utility.

Claims 27-45 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

4. If Applicant overcomes the rejection under 35 USC § 101, the rejection of claims 1-10 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule encoding the polypeptide encoded by SEQ ID NO: 31, does not reasonably provide enablement for a nucleic acid molecule that encodes a fragment of the polypeptide encoded by SEQ ID NO: 31 is applied to claims 27-35, for reasons of record set forth in Paper No. 9, 6/29/2001. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant argues that one skilled in the art can use well-established protocols to determine whether a claimed fragment has odorant-receptor activity. However, there is no functional limitation in claim 27, and at the time of filing one skilled in the art would not know how to use the claimed invention, thus there is insufficient guidance for one of skill in the art to generate a nucleic acid sequence encoding a fragment of a polypeptide other than those exemplified in the specification.

5. Claims 43-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

These are genus claims. In the specification (page 14, lines 2-8), Applicants disclose that variants of the polypeptide can be generated by substitutions, insertions or deletions, without disclosing any actual or prophetic examples on expected performance parameters of any of the possible muteins of SEQ ID NO: 31. The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to SEQ ID NO: 31. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art, the specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 31 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is vague and indefinite in that the claimed nucleic acid molecule comprises at least one exon-intron boundary. However, SEQ ID NO: 31 is a cDNA, and thus would not include introns, so it is unclear how it could comprise the exon-intron boundary, which is two nucleic acids, one in the exon, one in the intron. Claims 28-35 are rejected insofar as they depend on this limitation in claim 27.

Claim Rejections - 35 USC § 102

The rejection of claims 1-10 under 35 U.S.C. 102(a) as being anticipated by Celniker et al. (1998) has been applied to claims 27-35, 43-44, for reasons of record set forth in Paper No. 9, 6/29/2001.

Celniker teaches a nucleic acid sequence that would hybridize under conditions to produce a clear signal. Based on the indefinite nature of claim 27 (*supra*), and dependent claims, the nucleic acid of Celniker still falls within the limitations of the claims. Additionally, the nucleic acid of Celniker would expect to hybridize under the conditions set forth in claims 43-44.

Conclusion

7. Claims 27-45 are rejected.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

DAVID S. ROMEO
PRIMARY EXAMINER

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
February 27, 2002